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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,064	02/12/2002	Thomas Ciossek	038602-1324	4694

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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,064	CIOSSEK ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *23 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 6-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/12/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Election filed September 23, 2004 in response to the Office Action of August 25, 2004 is acknowledged and has been entered. Claims 1-4, 6-15 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claim 5 is currently under prosecution.

2. Applicant's election of Group 2, claim 5 without traverse is acknowledged.

Specification

3. The specification on page 25 states that "key amino acids of the catalytic domain are highlighted in bold italics" in Figure 1. However, Figure 1 shows no highlighted amino acids. Correction is required.

Claim Objections

4. Claim 5 is objected to because of an apparent typographical error. The claim reads "An isolated, enriched or purified purified MDK1 polypeptide". Deletion of the extra "purified" is required.

Claim Rejections - Double Patenting

5. The non-statutory double patenting rejection, whether of the obviousness type or non-obviousness type, is based on a judicially created doctrine grounded in public policy (a policy relected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 438, 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-

statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed b the assignee must fully comply with 37 CFR 3.73(b)

6. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1-5 of US Patent No. 6,361,984.

The claim is drawn to an isolated, enriched or purified MDK1 polypeptide. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim is generic to the species claims of US Patent No. 6,361,984 which claims three isolated, enriched or purified MDK1 polypeptide species and the species make obvious the claimed genus.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

8. Claim 5 is rejected under 35 USC 112, first paragraph because the specification, while enabling for an isolated, enriched or purified MKD1 polypeptide wherein said polypeptide comprises SEQ ID NO:2, 11 or 12, does not reasonably provide enablement for an isolated enriched or purified MDK1

polypeptide. The specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention commensurate in scope with this claim.

The claim is drawn to an isolated, enriched or purified MDK1 polypeptide. This means any MDK1 polypeptide as defined by the specification. The specification teaches that MDK1 receptor tyrosine kinases are proteins that are involved in signal transduction pathways (page 6 lines 7-8). Further, an MDK1 polypeptide is defined in the specification, on page 8, lines 14-22, as 2 or more contiguous amino acids set forth in a full length amino acid sequence of SEQ ID No: 2 or a functional derivative thereof. Further, the specification teaches that the MDK1 polypeptide can be encoded by a full length or any portion of a full-length nucleic acid sequence, so long as functional activity of the polypeptide is retained. It is noted that functional activity is not defined in any limiting fashion.
One cannot extrapolate the teachings of the specification to the scope of the claim because the claim as currently constituted reads on "functional" derivatives of SEQ ID NO:2 with neither structure nor function that has any relationship to SEQ ID NO:2 because a functional derivative is not defined in the specification in any limiting fashion and appears to encompasses "chemical derivatives," "fragment," "variant," "chimera," or "hybrids" (para 0270 of the published application). The specification defines a "chemical derivative" as a protein that contains additional chemical moieties not normally a part of the protein, defines a "fragment" as a polypeptide derived from the amino acid sequence having a length less than the full-length polypeptide from which it has been derived which retains a characterizing portion of the native protein, defines a "variant" polypeptide as one which either lacks one or more amino acids or contain additional or substituted

amino acids relative to the native polypeptide, while neither hybrid nor chimera are defined by the specification (paragraphs 0270-0300 of the published application). Thus, it is clear that as defined by the specification, an MDK1 polypeptide reads on every polypeptide which comprises two amino acids of SEQ ID NO:2 regardless of length, localization or function. Applicant has clearly not enabled all of these types of modified proteins. Evidence abounds which demonstrates that protein chemistry is probably one of the most unpredictable areas of biotechnology. Bowie et al (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out the instructions of the genome and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (col 1, p. 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (col 2, p. 1306). Given that SEQ ID NO:2 is a 998 amino acid protein, the claims as written read on undefined alterations of 996 amino acids and the effects of these alterations on protein structure and function cannot be predicted. Certainly it is well known that changes in even a few amino acid residues of a protein can result in dramatic changes in function and activity. For example, published patent application 20030105000

specifically teaches on page 73 that the SH2 domain of Grb14 is 81% similar to the SH2 domain of Grb7 on the amino acid level, but although Grb7 binds to ErbB2, Grb14 does bind to ErbB2. This change in specificity appears to be related to a 19% difference between the two proteins. It cannot be predicted what a change of 99.7% of the amino acids in the claimed MDK1 polypeptide from SEQ ID NO:2 would do to the structure and function of the currently claimed polypeptide. Further, Kopchick et al (US Patent No. 5,350,836) disclose several antagonists of vertebrate growth hormone that differ from naturally occurring growth hormone by a single amino acid (col 2, lines 37-48). Thus it is clear that even with a single amino acid change, the function of a protein can be substantially altered. Thus, it cannot be predicted how to use the broadly claimed MDK1 polypeptide, nor can it be predicted how to make the claimed MDK1 polypeptide since functional derivatives are not defined in a limiting fashion either in the specification or in the claim as currently constituted. . For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

9. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NOs:2, 11, 12 therefore the written description is not commensurate in scope with the claim to an isolated, enriched or purified MDK1 polypeptide as defined in the specification.

The claim as written encompasses polypeptides which vary substantially in length and also in amino acid sequence given the definition of a MDK1 polypeptide in the specification. In particular, an MDK1 polypeptide is defined in

the specification, on page 8, lines 14-22, as 2 or more contiguous amino acids set forth in a full length amino acid sequence of SEQ ID No: 2 or a functional derivative thereof. Further, the specification teaches that the MDK1 polypeptide can be encoded by a full length or any portion of a full-length nucleic acid sequence, so long as functional activity of the polypeptide is retained. It is noted that functional activity is not defined in any limiting fashion. Thus, it is clear that the claim as currently constituted reads on MDK1 polypeptides which are functional derivatives of SEQ ID NO:2 which have neither structure nor function that has any relationship to SEQ ID NO:2 because functional derivatives are not defined by the specification in any limiting fashion and appear to encompasses "chemical derivatives," "fragment," "variant," "chimera," or "hybrids" (para 0270 of the published application). The specification defines a "chemical derivative" as a protein that contains additional chemical moieties not normally a part of the protein, defines a "fragment" as a polypeptide derived from the amino acid sequence having a length less than the full-length polypeptide from which it has been derived which main retain a characterizing portion of the native protein, defines a "variant" polypeptide as one which either lacks one or more amino acids or contain additional or substituted amino acids relative to the native polypeptide, while neither hybrid nor chimera are defined by the specification (paragraphs 0270-0300 of the published application). Thus, it is clear that as defined by the specification, an MDK1 polypeptide reads on every polypeptide which comprises two amino acids of SEQ ID NO:2 regardless of length, localization or function.

However, the instant disclosure of SEQ ID NO:2 and the variants of SEQ ID NO:2, SEQ ID NOs 11 and 12 does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera. Although

drawn to the DNA arts, the findings of the courts in *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997 are clearly relevant to the instant claimed invention. The court found that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polypeptides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of three specific polypeptide sequences is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and that the

disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

10. Claim 5 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite in the recitation of the term MDK1 polypeptide as the sole means of identifying the claimed invention. Although an MDK1 polypeptide is defined in the specification on page 8, lines 14-22, as 2 or more contiguous amino acids set forth in a full length amino acid sequence of SEQ ID No: 2 or a functional derivative thereof, this definition is so broad that it is not possible to determine the metes and bounds of the patent protection sought. Further, the claim is objected to as being indefinite in the use of designation MDK1 as the sole means of identifying the claimed polypeptide. The use of laboratory designations only to identify a particular polypeptide renders the claim indefinite because different laboratories may use the same laboratory designations to define completely distinct polypeptides. Amendment of the claims to include, for example, unique identifiers such as SEQ ID NOs which unambiguously define the invention would obviate the instant rejection.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 5 is rejected under 35 U.S.C. § 102(b) as being anticipated by Sajjadi et al, (New Biologist, 1991, 3:769-778).

It is noted that an MDK1 polypeptide is defined in the specification, on page 8, lines 14-22, as 2 or more contiguous amino acids set forth in a full length amino acid sequence of SEQ ID No: 2

The claim is drawn to an isolated, enriched or purified MDK1 polypeptide.

Sajjadi et al teach a 983 amino acid sequence eph-related receptor tyrosine kinase which has 63.5% identity to Seq ID No. 2 (see Fig 2, pages 772-774) with numerous examples of 2 or more contiguous amino acids as set forth in the full length amino acid sequence of SEQ ID No: 2. All the limitations of the claim are met.

14. No claims allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 571-0787. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Susan Ungar
Primary Patent Examiner
December 2, 2004